Statement of Rep. Tom Davis
Ranking Republican Member
Committee on Oversight and Government Reform
Safe and Affordable Biotech Drugs – The Need for a Generic Pathway
March 26, 2007

Thank you Mr. Chairman for holding today's hearing to consider the implications of creating a regulatory pathway for approval of follow-on biologics. This is a very important subject and worthy of this Committee's attention.

Mr. Chairman, you have long been a leader on improving access to pharmaceutical drugs. Indeed, there is near universal agreement that the Hatch-Waxman Act has been extremely effective in allowing generic drugs to come to market and compete with the brand name drugs. This competition has benefited countless citizens as well as the federal government by using natural market economics to bring down the price of prescription medicine. You are to be commended for your leadership in improving access to these life saving medications.

It is my understanding that you have recently introduced legislation which would in fact create a regulatory pathway for FDA to approve follow-on biologics. We have been reviewing your legislation with interest, as we expect it will inform today's discussion. I look forward to exploring your proposal further.

For now, let me just offer a few preliminary thoughts on this complex subject.

The first principal guiding this effort should be to foster innovation and the discovery of new cures. After all, if there is no new therapeutic, by definition, there can be no follow- on. Accordingly, we need to protect the intellectual property (IP) of innovator firms. Given the high cost of research, development, manufacturing, and regulatory hurdles, IP protections are clearly an important factor for bio-tech start-ups when they are securing venture capital and pursuing partnerships with larger firms. Today, we will hear from economist Henry Grabowski who will explain that increased patent uncertainty and IP litigation would have a significant and negative effect on capital market decisions for emerging private and public biotech firms. He will explain that if the federal government either weakens patent protections or increases the chance of litigation, there will likely be a corresponding decrease in investment and therefore less research and development of biologics.

It would be tragic if legislation intended to increase access to medicine would have the unintended result of stifling innovation, preventing the discovery of cures for presently terminal diseases.

I hope that you would agree with me, Mr. Chairman, about the importance of fostering a vibrant and innovative culture, where we encourage our brightest minds and daring entrepreneurs to do the research and provide the investment, so that we may some day discover the cure for cancer or Lou Gehrig's disease.

Reflecting on the Hatch-Waxman Act, you got it right when you recognized the importance of balancing the twin goals of bringing generic drugs to market while at the same time leaving

intact the financial incentive for research and development. One of the keys to this successful balance in that legislation was the guarantee of five years of market exclusivity for innovator companies. Incidentally, European Union regulators currently provide 10 years of market exclusivity for innovator drugs. Some amount of market exclusivity for the innovator is necessary under any regulatory pathway for follow-on biologics.

The second imperative is to provide a mechanism so the FDA is able to guarantee the safety and efficacy of follow-on biologics. To do so, we have to recognize the fundamental differences between biologics and chemical based pharmaceuticals. What has proven to be successful in the case of traditional drugs is not necessarily transferable to the science of biologics.

For instance, it is currently possible to know the complete character of a small-molecule drug. This knowledge enables the FDA to approve generic drugs with the same characteristics as the innovator drug, without requiring the generic company to test and prove the drug's efficacy and safety again. However, current science has not advanced sufficiently to give us the same confidence that a follow-on biologic is identical to a previously approved biologic based on molecular structure alone. Unlike traditional drugs, which are chemically based, biologics are made from living organisms. Even minor variations in manufacturing processes can have a significant impact on the final character and consistency of the biologic and its effect on the human body.

[reference slide here] This diagram comparing a biologic used to treat anemia, and a traditional drug that treats peptic ulcer disease, demonstrates the differences between traditional chemical drugs and biologic therapies. As you can see, the biologic is

significantly more complex than a traditional drug, having a molecular weight of 30,000 vs. 351.

This is a critical distinction between traditional generic drugs and follow-on biologics. Any regulatory pathway must take full account of this distinction, which for now seems to point to the inescapable conclusion that clinical trials on some level will be essential to ensure the safety and efficacy of follow-on biologic products.

With that, I want to thank you again for spurring a discussion on this important subject. I look forward to hearing from our distinguished panel of witnesses.